

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 17-1648V

Filed: March 27, 2025

* * * * *
ALINA DERKACH, *
as administrator and legal representative *
of ESTATE OF E.E.D., *
*
Petitioner, *
v. *
*
SECRETARY OF HEALTH *
AND HUMAN SERVICES, *
*
Respondent. *
* * * * *

Elizabeth Muldowney, Esq., Sands Anderson PC, Richmond, VA for petitioner.
Emilie Williams, Esq., U.S. Department of Justice, Washington, DC, for respondent.

DECISION¹

Roth, Special Master:

On November 1, 2017, Alina Derkach (“petitioner”) filed a petition on behalf of her minor son, E.E.D., for compensation pursuant to the National Vaccine Injury Compensation Program.² ECF No. 1. Petitioner alleges that E.E.D. developed a bowel obstruction and/or intussusception requiring surgical intervention with resultant complications as a result of the Rotarix (live rotavirus vaccine), Pediarix (diphtheria, tetanus, acellular pertussis, recombinant hepatitis B, and inactivated poliovirus vaccine combined), and/or haemophilus influenza type B (“Hib”) vaccines he received on November 5, 2014. *See* Amended Petition (“Am. Pet.”), ECF No. 75. Sadly, E.E.D. passed away on November 4, 2023. Petitioner’s Exhibit (“Pet. Ex.”) 45, ECF No. 69.

¹ Because this Decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims’ website, and/or at <https://www.govinfo.gov/app/collection/uscourts/national/cofc>, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the Decision will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), the parties have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. Any changes will appear in the document posted on the website.

² National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all “§” references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2018).

I extend my sincerest sympathies to Mr. and Mrs. Derkach on the loss of their son and for what E.E.D. endured during his short life. However, my decision must be based on the evidence and on the law. Upon careful evaluation of all the evidence submitted, I find that petitioner has not provided preponderant evidence that the vaccines E.E.D. received on November 5, 2014 caused him to suffer the injuries alleged.

I. Procedural History

Petitioner filed her petition³ on November 1, 2017, and it was assigned to the undersigned the following day. ECF Nos. 1, 4.

Petitioner filed medical records on November 3, 2017. Pet. Ex. 1-16, ECF Nos. 6-8. Respondent filed his Rule 4(c) Report on April 23, 2018 recommending against compensation. ECF No. 12.

On October 22, 2018, petitioner filed an expert report and supporting medical literature. Pet. Ex. 17-30, ECF Nos. 17-18. Respondent filed a responsive expert report on May 31, 2019. Respondent's Exhibits ("Resp. Ex.") A-J, ECF No. 23.

The parties exchanged further expert reports on August 9, 2019, October 21, 2019, and December 20, 2019. Pet. Ex. 34-37, ECF Nos. 29, 36; Resp. Ex. K-M, ECF No. 35.

A Rule 5 conference was held on February 6, 2020 and further expert reports were ordered. ECF No. 38. Petitioner filed a supplemental expert report on May 6, 2020. Pet. Ex. 38-40, ECF No. 40. Respondent filed a responsive expert report and supporting literature on July 6, 2020. Resp. Ex. N-U, ECF No. 42.

On August 6, 2020, petitioner filed further medical records and a status report confirming that the record was complete and requesting that an entitlement hearing be scheduled. Pet. Ex. 41-44, ECF Nos. 43-45. A status conference was held. Petitioner's counsel advised of the passing of their expert. Petitioner's counsel requested time to discuss with her client and with respondent how to proceed. ECF No. 46.

Over the next year, the parties filed status reports on January 11, 2021, January 19, 2021, March 18, 2021, May 17, 2021, July 16, 2021, and August 30, 2021. On September 29, 2021, petitioner filed a status report advising that she was not able to find another expert and requested that the matter proceed to a ruling on the record. ECF Nos. 47-52, 55.

³ This case was not filed as an on-Table Injury. The Vaccine Injury Table provides for intussusception as a Table injury for the first two rotavirus vaccinations. 42 C.F.R. § 100.3(a)(XI)(c)(4). However, the Table's Qualifications and Aids to Interpretation ("QAI") state in relevant part: "[T]he following shall not be considered to be a Table intussusception: Onset in a person with underlying conditions or systemic diseases associated with intussusception (such as cystic fibrosis, celiac disease, or Kawasaki disease)." § 100.3(c)(4)(ii)(E). The QAI additionally excludes a Table intussusception if "[onset occurs] within 14 days after an infectious disease associated with intussusception, including viral disease ..., which may be demonstrated by clinical signs and symptoms and need not be confirmed by culture or serologic testing." § 100.3(c)(4)(ii)(B). Because both of these circumstances apply to E.E.D., petitioner must pursue an off-Table claim.

Petitioner filed a Motion for Ruling on the Record on January 25, 2022. Motion, ECF No. 59. Respondent filed his response on March 4, 2022. Response, ECF No. 62. Petitioner filed her reply on April 15, 2022. Reply, ECF No. 65.

Petitioner advised via status report filed on November 29, 2023 that E.E.D. had passed away. ECF No. 66. The caption was amended to reflect petitioner as the administrator and legal representative of E.E.D.'s estate. ECF Nos. 72-75.

This matter is ripe for Decision.

II. Medical Terminology

An intestinal obstruction, also referred to as a “small bowel obstruction”, is a blockage of the intestine that can be either mechanical or nonmechanical. A “kink” of the bowel, also known as a volvulus, is a type of mechanical obstruction due to a knotting and twisting of part of the gastrointestinal tract.⁴ Resp. Ex. U.⁵

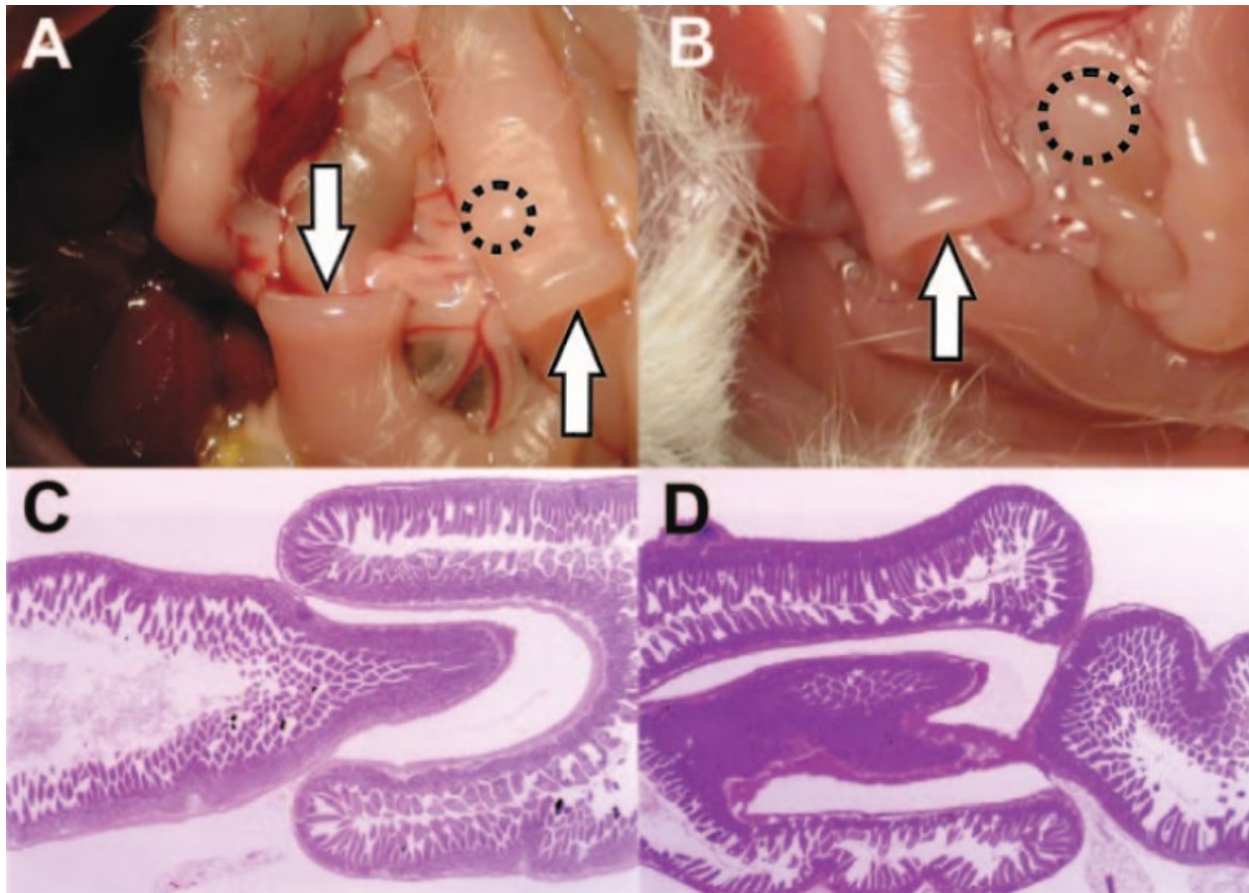
Intussusception is where one part of the intestine telescopes or folds into the section next to it, essentially sliding inside itself causing a blockage. It usually involves the small bowel and can happen in infants, children, and adults. Pet. Ex. 37 at 4;⁶ Resp. Ex. H at 1, 2.⁷ The part that prolapses into the other is called the intussusceptum. The part that receives it is the intussusciens, thus the name intussusception. Resp. Ex. H at 2.

⁴ Intestinal obstruction, DORLAND'S ILLUSTRATED MEDICAL DICTIONARY 1292 (33rd ed. 2020) [hereinafter DORLAND'S]; Volvulus, DORLAND'S 2040.

⁵ Hilbert S. de Vries et al., *Cecal Volvulus Caused by a Large Uterine Leiomyoma*, 10 INT'L J. SURGERY CASE REPORTS 97 (2015), filed as “Resp. Ex. U”.

⁶ Janice A. Kelly, *Intussusception*, in PEDIATRIC GASTROENTEROLOGY: THE REQUISITES IN PEDIATRICS (Chris A. Liacouras & David A. Piccoli, 2008), filed as “Pet. Ex. 37”.

⁷ Shobhit Jain & Michelle J. Haydel, *Child Intussusception*, STAT PEARLS PUBLISHING (2018), filed as “Resp. Ex. H”.



This image is copied from Pet. Ex. 27. Quadrant A shows a double intussusception, and quadrant B shows a single intussusception. The arrows indicate the direction of the intussusception. Pet. Ex. 27 at 3, Fig. 1.

Intussusception is the most common cause of intestinal obstruction in young children and is most often idiopathic. Pet. Ex. 28 at 1.⁸ Roughly 50% of children with intussusception shed virus in their stool. Adenovirus, enterovirus, and cytomegalovirus are the most common viruses implicated. *Id.*

A child with intussusception presents with irritability, vomiting, and bloody or “currant jelly stool” believed to be a mixture of blood, stool, and mucus. Pet. Ex. 37 at 5.⁹ Typical presentation, present in 30-60% of infant patients, includes bouts of colicky pain, vomiting, pallor, poor perfusion, and passage of currant jelly stool with periods of quiet. Up to 20% have no pain. *Id.*

On abdominal radiographs, the pathognomonic sign of intussusception is a crescent shaped mass within the colon, particularly the transverse colon, just beyond the hepatic flexure. The absence of bowel gas in the ascending colon is one of the most specific signs of intussusception on imaging. Ultrasound (“US”) is the preferred testing as x-rays have low

⁸ Christine G. Robinson et al., *Evaluation of Anatomic Changes in Young Children with Natural Rotavirus Infection: Is Intussusception Biologically Plausible?*, 189 J. INFECTIOUS DISEASES 1382 (2004), filed as “Pet. Ex. 28”.

⁹ Kelly, *supra* note 6.

sensitivity. Pet. Ex. 35 at 2.¹⁰ Ultrasounds can also assist in evaluating the preferred intervention for reducing the intussusception. *Id.* at 2-3.

Rotavirus is the most common cause of diarrhea in infants and children. Pet. Ex. 25 at 1.¹¹ Studies have shown an increased risk of intussusception following RotaTeq and Rotarix vaccines within 7 days of vaccination. Resp. Ex. F at 7.¹² While these earlier versions of the rotavirus vaccine, which are no longer used, were thought to cause intussusception, current rotavirus vaccines are not clearly linked. Resp. Ex. H at 2.¹³

Cri-du-Chat Syndrome is a genetic disease resulting from the deletion or partial deletion of part of chromosome 5. Its clinical symptoms include a high-pitched cat cry, distinct facial dysmorphism, microcephaly, and severe psychomotor and mental disability. Pet. Ex. 39 at 1.¹⁴ Other malformations of the cardiac, neurological, and renal systems may be present. *Id.* at 1, 2. Recurrent respiratory and intestinal infections are reported during the first year of life. *Id.* at 2. In one study of eighty children, 92% experienced neonatal complications at birth including poor sucking, respiratory distress, and jaundice. Resp. Ex. C at 4.¹⁵ Twenty-seven percent of the children with unbalanced translocation (not isolated deletion) had gastrointestinal tract abnormalities including intestinal malrotation, Hirschsprung disease,¹⁶ adynamic ileus, and bowel obstruction. *Id.* at 4-5.

Necrotizing enterocolitis (“NEC”) is a disease affecting primarily premature, stressed infants. Distinguishing NEC from intussusception can be difficult because the symptoms significantly overlap with both involving abdominal distention,¹⁷ vomiting or gastric retention, and gastrointestinal bleeding. Pet. Ex. 29 at 1, 2.¹⁸

III. Background

¹⁰ Kimberly E. Applegate, *Intussusception in Children: Evidence-Based Diagnosis and Treatment*, 39 PEDIATRIC RADIOLOGY S140 (2009), filed as “Pet. Ex. 35”.

¹¹ Judith Koch et al., *Risk of Intussusception After Rotavirus Vaccination*, 114 DEUTSCHES ARZTEBLATT INT’L 255 (2017), filed as “Pet. Ex. 25”.

¹² Anthony T. Manning & Danny C. Little, *Intussusception in Infants and Children*, in PEDIATRIC GASTROINTESTINAL AND LIVER DISEASE (Robert Wyllie et al., 2016), filed as “Resp. Ex. F”.

¹³ Jain & Haydel, *supra* note 7.

¹⁴ Paola Cerruti Mainardi, *Review: Cri du Chat Syndrome*, 1 J. RARE DISEASES 33 (2006), filed as “Pet. Ex. 39”.

¹⁵ Louise E. Wilkins, Ph.D. et al., *Clinical Heterogeneity in 80 Home-Reared Children with Cri du Chat Syndrome*, 102 J. PEDIATRICS 528 (1983), filed as “Resp. Ex. C”.

¹⁶ Hirschsprung disease involves dilatation of a section of the colon due to congenital absence of intrinsic ganglion cells in the myenteric and submucosal plexuses of the next distal segment; the aganglionic part is abnormally narrow, and its loss of motor function causes massive hypertrophic dilatation of more proximal segments. The condition appears soon after birth, is more common in males, and causes extreme constipation, abdominal distention, and sometimes vomiting; when severe, it may result in growth retardation. It is sometimes divided into short-segment and long-segment forms, may occur as an isolated trait or in conjunction with other congenital anomalies, and may show dominant, recessive, or multigenic patterns of inheritance, with gender-dependent penetrance. It has been associated with mutations in one or a combination of several genes, including genes encoding either a protein-tyrosine kinase receptor (*RET*) or one of its ligands, and genes encoding either endothelin-3 (*EDN3*) or its receptor (*EDNRB*). Congenital megacolon, DORLAND’S 1106.

¹⁷ Distention refers to enlargement. Distention, DORLAND’S 550.

¹⁸ Shinichiro Hirokawa et al., *Ileoileal Intussusception and Ileal Stricture Associated with Necrotizing Enterocolitis in a Premature Infant: Report of a Case*, 31 SURGERY TODAY 1097 (2001), filed as “Pet. Ex. 29”.

A. E.E.D.'s History Prior to the Subject Vaccination

E.E.D. was the product of a pregnancy complicated by low fetal growth and ultrasound findings of microcephaly, cerebral hypoplasia, and micrognathia. Pet. Ex. 5 at 5; Pet. Ex. 6 at 35; *see generally* Pet. Ex. 3; Pet. Ex. 4. E.E.D. was born on August 28, 2014 at 41 weeks gestation via spontaneous vaginal delivery. Pet. Ex. 5 at 2. At birth, microcephaly, micrognathia, and dysmorphic features were noted. Pet. Ex. 6 at 35. E.E.D. was transferred to the neonatal intensive care unit ("NICU") where he remained for the first several weeks of his life. Genetic testing showed Cri-du-Chat syndrome, a deletion of part of chromosome 5 associated with hoarse cry, failure to thrive, feeding difficulties, and intellectual disabilities. *Id.* at 34, 37, 1644, 1655, 1751. Additionally, E.E.D. had brain anomalies, anemia, feeding problems, gastroesophageal reflux, and congenital anomalies including ventricular septal defect ("VSD"), laryngomalacia, and stridor. *Id.* at 1-2, 1638-39. His anomalies caused feeding difficulties, and he required a nasogastric tube and nasal cannula for respiratory support. *Id.* at 19-20, 23, 1640-41, 1751.

At five days old, E.E.D. developed abdominal distention and possible bowel obstruction on x-ray. He was diagnosed with necrotizing enterocolitis ("NEC"), and antibiotics were started. Pet. Ex. 6 at 17, 23, 91-92, 1614-15. Repeat x-rays showed possible sentinel bowel loop. *Id.* at 14, 131, 1620, 1893. A nuclear medicine scan on September 20, 2014 revealed gastroesophageal reflux with aspiration and a gastrostomy tube ("G-Tube")¹⁹ was placed for feeding and fundoplication²⁰ performed on October 2, 2014. *Id.* at 19-23, 40, 1111, 1640. Antibiotics for suspected aspiration pneumonia were given. *Id.* at 21.

E.E.D. was medically fragile with pain and agitation. He was maintained on fentanyl with rescue morphine. Pet. Ex. 6 at 54. He received therapies for significant shoulder winging and difficulty with upper extremity extension. He had low muscle tone with significant tightness of the shoulders, hips, knees, and elbows. He also had neurological impairments. *Id.* at 48. He was discharged home on October 17, 2014 with a G-tube. *Id.* at 43.

E.E.D. was presented to his pediatrician on October 20, 2014. It was noted that after birth he admitted to the NICU for hypotonia and was discharged three days ago. He had Cri-du-Chat syndrome, developmental delay, G-tube feeding, congenital stridor, VSD, poor weight gain, and microcephaly. He had soft stools a couple times a day but cries and "tends to be quite fussy". Pet. Ex. 9 at 1. He was to return in three days to determine if an increase in feeds was necessary. *Id.* at 2. The pediatrician advised that phenobarbital for fussiness could not be started outpatient due to risk of apnea and would have to be done as an inpatient. *Id.* at 1, 2. He received his HBV vaccine just prior to hospital discharge, and it was recommended that the vaccine schedule start in approximately 2 weeks. *Id.* at 2.

¹⁹ A gastrostomy tube is inserted through a stoma on the body surface into the stomach in a gastrostomy, which is the surgical creation of an artificial opening into the stomach. Gastrostomy tube, DORLAND'S 1946; Gastrostomy, DORLAND'S 758.

²⁰ Fundoplication is plication of the fundus of the stomach around the lower end of the esophagus, done as treatment for reflux esophagitis. Fundoplication, DORLAND'S 741.

E.E.D. was presented to the pediatrician on October 23, 2014 with continued fussiness, gassiness, and discomfort. Even with fundoplication, his mother and aunt thought he still had reflux when lying down. Yellow, watery, and loose stools were reported without blood or mucus. His mother was also concerned about the area around the G-tube being red. Pet. Ex. 9 at 2. On examination his abdomen was soft and nondistended, but he fussed with palpation. *Id.* at 3. G-tube care was discussed, as was E.E.D.'s fussiness being characteristic of Cri-du-Chat so he may not have been in pain or uncomfortable. Peppermint tea was suggested. *Id.*

He was seen at Spokane Ear, Nose and Throat Clinic and Surgical Specialists for laryngomalacia on October 28, 2014. He was 8 weeks old and doing well with his G-tube/fundoplication. He had a noisy, wet upper airway but no regurgitation, cyanosis, apnea, or deep sternal retractions noted by mother. He had a complex history of chromosome 5 deletion, VSD, microcephaly, GERD, and severe micrognathia with laryngomalacia. He was gaining weight slowly. Pet. Ex. 10 at 1. The assessment was respiratory insufficiency, major anomalies of jaw size, and Cri-du-Chat syndrome but no evidence of life-threatening airway events. *Id.* at 2. He was not expected to have an easy transition to oral feedings, but they were hopeful he would eventually swallow safely. *Id.*

On October 30, 2014, E.E.D. was presented to the pediatrician for his 8-week well check. He was doing well according to cardiology and ENT check-ups. His mother was concerned about a facial and neck rash. He had not gained weight. Stools were soft but not runny. E.E.D. slept all night but for diaper changes. Pet. Ex. 9 at 4. Vaccines were declined but his mother planned to discuss vaccinations with her husband. *Id.* at 7. His feeds were to increase with weight recheck in a week. *Id.*

B. E.E.D.'s History Following the Subject Vaccination

On November 5, 2014, E.E.D. was presented to the pediatrician for weight check. He was tolerating his feeding regimen, stools had normalized, and he was seen by the surgeon earlier that day for G-tube concerns. Pet. Ex. 9 at 8. He had excellent weight gain. *Id.* at 9. He received the Pediarix, Hib, and Rotarix vaccines at this visit and planned to receive the Prevnar vaccine in two weeks at his next recheck. *Id.*; Pet. Ex. 12 at 1.

E.E.D. was presented to the ER on November 9, 2014. His mother reported multiple episodes of watery, non-bloody, non-mucoid diarrhea that began around noon yesterday and continued through the night and early morning. She was concerned for dehydration due to dry and tacky mouth, so she brought him to the ER. Pet. Ex. 6 at 2009-10. He was fed breast milk only and had no fever or sick contacts. His G-Tube site was improving, and redness was decreasing. *Id.* at 2010. Upon examination, his abdomen was distended and firm but not rigid, and he had decreased bowel sounds. *Id.* at 2012. Venting the G-tube released a small amount of gas and stomach content but did not significantly reduce the abdominal distention. *Id.* The assessment was a 2-month-old with loose stool and poor hydration. *Id.* at 2013. He was rehydrated with minimal response. His abdomen was "remarkably distended" and x-ray showed a small bowel obstruction. Abdominal distention was enough to decrease lung volume and increase respiratory rate. The differential diagnoses included simple acute viral gastroenteritis, small bowel obstruction, intestinal perforation, or other intra-abdominal process. He was

afebrile, with normal white blood cell count. He was admitted to the Pediatric Intensive Care Unit (“PICU”) *Id.*

An abdominal x-ray showed gastrostomy tube and “[m]ultiple loops of distended small bowel with multiple air-fluid levels consistent with small bowel obstruction”. The impression was small bowel obstruction without pneumatosis or intra-abdominal free air. Pet. Ex. 6 at 2029, 2034. An exploratory laparotomy²¹ was done that day, which showed a kink in the small bowel at the terminal ileum that was easily reduced. *Id.* at 2020-21. In the days that followed, E.E.D. required mechanical ventilation. He tested positive for enterovirus and rhinovirus with fever and sepsis. *Id.* at 2050-52. It was noted in the medical record that enterovirus was “[l]ikely the cause of his ileus/SBO”. *Id.* at 2503. Abdominal ultrasounds performed on November 10, November 13, and November 14, 2014 showed numerous loops of fluid filled bowel in the abdomen. *Id.* at 2059-62. His clinical status worsened with increasing fever and bloody diarrhea. Imaging showed severe colitis causing his abdominal distention. *Id.* at 2511-12.

Additional surgery was performed on November 23, 2014 due to suspicion of necrotizing enterocolitis with symptoms of ongoing abdominal distention, sepsis, and bloody stools. The operative report documented extensive adhesions throughout the entire abdomen involving mostly the small bowel. Several parts of the small bowel contained “thick, indurated, hyperemic dense adhesions”. Pet. Ex. 6 at 2020, 2068-69. No report of or findings of intussusception were noted. *Id.* at 2069-70.

E.E.D. remained hospitalized until December 22, 2014. He required IV fluids, mechanical ventilation, seizure medication, a PICC line and multiple courses of antibiotics. He required two ECHOs for bacteremia. Pet. Ex. 6 at 2019-20. He was planned for re-anastomosis in early January following his ileostomy and mucous fistula. He had underlying tracheomalacia. He required methadone to wean off the narcotic medications he had been taking during hospitalization. He had PICC line infections with enterococcus and MSSA requiring removal and reinsertion of his PICC line prior to discharge. *Id.*

On January 5, 2015, E.E.D. was presented to the pediatrician for follow up of a prolonged hospitalization for kinked bowel with resection. He was weaning from narcotics and sedation and was fussy. Prevnar 13, Hib, and Pediarix vaccinations were administered at this visit. Pet. Ex. 9 at 10, 302; Pet. Ex. 12 at 1. Two days later, he was presented to his pediatrician again for a sick visit with symptoms of fever, cough, and congestion. Pet. Ex. 9 at 14-15. Because he was a high-risk patient, he was sent to the hospital. *Id.* at 15.

On January 16, 2015, E.E.D. was admitted to the hospital for re-anastomosis²² of the ileostomy and mucous fistula. Pet. Ex. 6 at 5433, 5445-47. Follow up abdominal x-ray on February 5, 2015 showed no evidence of obstruction or anastomotic structure. Pet. Ex. 6 at 5801, 5806.

²¹ A laparotomy involves surgical incision into the abdominal cavity. Laparotomy, DORLAND’S 991.

²² Anastomosis refers to a connection between two vessels or other tubular structures or an opening created by surgical, traumatic, or pathological means between two normally separate spaces or organs. Anastomosis, DORLAND’S 74.

E.E.D.'s medical course thereafter was complicated by many visits to the ER and prolonged hospitalizations for infections including RSV, fever, breathing problems, watery diarrhea and vomiting, line infections, blood transfusions for anemia, C. Difficile requiring two fecal transplants, bowel obstructions requiring additional laparotomies, other aggressive medical therapies, and enteral support with PICC lines for home TPN and antibiotics. *See, e.g.*, Pet. Ex. 6 at 5786, 5814-15, 5820, 5825, 5831, 7236, 7240, 7244, 7262, 7501, 7507; Pet. Ex. 9 at 16-45. He was also diagnosed with pancreatic deficiency and Hirschsprung's disease. Pet. Ex. 6 at 7517, 7620.

Sadly, E.E.D. passed away on November 4, 2023 at the age of 9. The cause of death was listed as A) septic shock related to intra-abdominal infection, interval 36 hours; B) Anastomotic leak from previous extensive exploratory laparotomy, lysis of adhesions, and small bowel resection, interval 36 hours; C) High grade small bowel obstruction, interval 8 days; and D) Short gut syndrome, interval 9 years. Other conditions contributing to death included Cri-du-Chat syndrome, Hirschsprung's disease, SLC9A3 mutation, and developmental delay. Pet. Ex. 45.

C. Affidavits

1. Affidavit of Alina Derkach

Alina Derkach is E.E.D.'s mother. Pet. Ex. 1. According to Ms. Derkach, E.E.D. spent 8 weeks in the hospital following his birth due to oxygen and feeding issues. He was doing great when discharged and getting the proper nutrition via G-tube. *Id.* at 1.

Ms. Derkach affirmed taking E.E.D. to the pediatrician on November 5, 2014 for follow up and vaccinations. He received the oral rotavirus, Pediarix, and Hib vaccines and had some fever and irritability following the vaccinations. On November 8, 2014, he started to have diarrhea. She contacted the pediatrician's office to advise that E.E.D. had severe diarrhea and was inconsolable. Pet. Ex. 1 at 1.

Ms. Derkach affirmed that on November 9, 2014, E.E.D. was presented to the ER and was diagnosed with a small bowel obstruction "about 5 cm from the ileocecal valve and severe dehydration." Pet. Ex. 1 at 1. An exploratory laparotomy was performed that night and E.E.D. was then admitted to the PICU. *Id.* at 1-2. He had a lot of complications after the surgery including respiratory failure and tachycardia, requiring extended intubation and a central venous catheter. *Id.* at 2. E.E.D. continued to have abdominal pressure and was thought to have a perforation. He developed a fever and his abdomen became distended. A CT scan on November 14, 2014 showed no signs of obstruction. On November 19, 2014, the doctor advised that E.E.D. had developed severe colitis which likely caused his "abdominal extension and not another obstruction." *Id.* He continued to have fever and bloody stools and the doctors advised that he was at increased risk for additional complications and recommended another exploratory laparotomy. E.E.D.'s ileum was resected, and ileostomy performed. An appendectomy was done at that time as well. E.E.D. had a colostomy bag for a few months with some additional complications but began to stabilize and was taken home on December 22, 2014. Pet. Ex. 1 at 2.

Ms. Derkach affirmed that E.E.D. continued to have loose stools from having his large intestine and colon removed. He had food sensitivities, would get severe diarrhea with a minor cold, needed daily medication for his gut, and still had a G-tube. Pet. Ex. 1 at 2. His life was very complicated mostly with gut issues because he did not absorb as much as a typical child. He was in and out of the hospital for stomach and intestinal issues. *Id.*

Ms. Derkach believes “that had it not been for the Rotavirus vaccination that [E.E.D.] received on November 4, 2014, he would never have developed a bowel obstruction and resulting surgery.” Pet. Ex. 1 at 2.

2. Affidavit of Ervin Derkach

Mr. Derkach is E.E.D.’s father. Mr. Derkach similarly affirmed that E.E.D. spent 8 weeks in the NICU after birth due to oxygen and feeding issues. Pet. Ex. 2 at 1. After discharge, he was doing great and getting proper nutrition through his G-tube. He received the oral rotavirus, Pediarix, and Hib vaccines on November 5, 2014. *Id.*

According to Mr. Derkach, E.E.D. had a fever and irritability following his vaccinations then began to have severe diarrhea and was inconsolable on November 8, 2014. His wife told him she called the pediatrician. Pet. Ex. 2 at 1. Mr. Derkach stated he was at work during the daytime, so his wife usually took care of E.E.D. and took him to his appointments. *Id.*

The remainder of his affidavit is the same as his wife’s. Pet. Ex. 2 at 1-3.

D. VAERS Report

Petitioner completed a VAERS report on January 24, 2016. Pet. Ex. 14. According to the report, E.E.D. received DTaP, Hep B, and Pediarix vaccines on October 28, 2014 at 11:30am with the adverse event onset on October 28, 2014 at 3pm. The adverse event was described as “Inconsolable, diarrhea, temperature” with “[s]urgery on 11/09/2014 for a kinked intestine, ileostomy and colostomy placed, caused colitis.” *Id.* at 1. Medical records were attached.

IV. Expert Opinions

A. Petitioner’s Expert, Dr. John Santoro

Dr. Santoro obtained his B.A. in biology from LaSalle College in 1973 and his D.O. from Philadelphia College of Osteopathic Medicine in 1978. Pet. Ex. 18 at 1. He completed an internship at John F. Kennedy Memorial Hospital from 1978–79 and performed his residency in internal medicine at the University of Medicine and Dentistry at the NJ School of Osteopathic Medicine from 1979–81. *Id.* Dr. Santoro also completed a fellowship in gastroenterology at the University of Medicine and Dentistry NJ School of Osteopathic Medicine from 1981–83. *Id.* at 2. He is board certified in internal medicine and gastroenterology. *Id.* He served as a clinical associate professor of medicine at Rowan University School of Osteopathic Medicine since 1983, in addition to being a clinician at Atlantic Gastroenterology Associates. *Id.* at 1, 3. Dr. Santoro has since passed away.

Dr. Santoro wrote four reports in this matter. Pet. Ex. 17; Pet. Ex. 34; Pet. Ex. 36; Pet. Ex. 38. In Dr. Santoro's opinion, E.E.D. suffered an intussusception and later NEC requiring surgery as a result of the rotavirus vaccine he received on November 5, 2014.

Dr. Santoro provided a cursory medical summary of E.E.D.'s medical history prior to the November 5, 2014 rotavirus vaccine which included that he was born with microcephaly, mild micrognathia, and Cri-du-Chat syndrome and spent 8 weeks in the NICU before being discharged home. Pet. Ex. 17 at 3; Pet. Ex. 38 at 2. He explained the clinical features of Cri-du-Chat but said that "bowel obstruction is not reported as a prominent feature of this syndrome". Pet. Ex. 38 at 2. Thus, he did not feel as though Cri-du-Chat was the cause of E.E.D.'s bowel obstruction. *Id.* He detailed E.E.D.'s history from the date of the vaccinations onward. Pet. Ex. 17 at 3-4; *see also* Pet. Ex. 34 at 1-2.

Dr. Santoro described intussusception as a rare bowel obstruction where the bowel folds or telescopes in on itself and is most common in young children. Pet. Ex. 17 at 5. The most common place for the intussusception to occur is where the small bowel joins the large bowel or colon, although it can occur in other parts of the intestine as well. Most people fully recover with prompt treatment, but a partial or incomplete intussusception can resolve spontaneously. "Infants with intussusception may become ill with vomiting, abdominal pain, and may also have blood in the stool." *Id.* Most often, no cause is identified. Intussusception has been associated with structural abnormalities and infection, such as adenovirus. It can be treated by a radiologist by unfolding the intestine to normal position with an enema of air or fluid under pressure. If unsuccessful, surgery is required to unfold or resect that part of the intestine causing the blockage. *Id.*; *see also* Pet. Ex. 38 at 2; Pet. Ex. 40.²³

He then discussed the history of various vaccines for rotavirus, including RotaShield and Rotateq, which were reported to be associated with intussusception. Pet. Ex. 17 at 5-6; Pet. Ex. 19.²⁴ Dr. Santoro submitted that VAERS has a reported 584 "confirmed intussusception events after administration of the Rotateq vaccine reported" between 2006 and 2012. *Id.*

Dr. Santoro quoted the package insert for the Rotarix vaccine, which is the vaccine E.E.D. received. Pet. Ex. 17 at 7; Pet. Ex. 20 at 5.²⁵ Based on the studies cited within the package insert, Dr. Santoro claimed that intussusception was "observed in temporal association within 31 days following the first dose of [Rotarix], with a clustering of cases in the first 7 days." *Id.* (emphasis in original). There is also support for intussusception within the first 7 days after the second dose of Rotarix. *Id.*; *see also* Pet. Ex. 21;²⁶ Pet. Ex. 22;²⁷ Pet. Ex. 25.²⁸ According to Dr.

²³ Roben ECZ & Horowitz R, *Rate of Spontaneous Resolution of Idiopathic Ileocolic Intussusception*, 7 ACAD. J. PEDIATRICS & NEONATOLOGY 18 (2018), filed as "Pet. Ex. 40".

²⁴ Perina Haber, MPH et al., *Intussusception After Rotavirus Vaccines Reported to US VAERS, 2006-2012*, 131 PEDIATRICS 1042 (2013), filed as "Pet. Ex. 19".

²⁵ GlaxoSmithKline, *Rotarix Package Insert*, (2016), filed as "Pet. Ex. 20".

²⁶ Manish M. Patel et al., *Intussusception Risk and Health Benefits of Rotavirus Vaccination in Mexico and Brazil*, 364 NEW ENG. J. MED 2283 (2011), filed as "Pet. Ex. 21".

²⁷ Harry B. Greenberg, M.D., *Rotavirus Vaccination and Intussusception—Act Two*, 364 NEW ENG. J. MED 2354 (2011), filed as "Pet. Ex. 22".

²⁸ Koch et al., *supra* note 11.

Santoro, the first week after receipt of rotavirus vaccination is the most common time for intussusception to occur. Pet. Ex. 17 at 11.

Dr. Santoro also cited *Weintraub*, which discussed the risk of intussusception following the monovalent rotavirus vaccination and found “a significant increase in the rate of intussusception after vaccination. After two doses of the monovalent Rotavirus vaccine, the estimated risk was 5.3 per 100,000 infants vaccinated.” Pet. Ex. 17 at 8; Pet. Ex. 23.²⁹ Similarly, *Yih* found that the rotavirus vaccine “was associated with an approximate 1.5 . . . excess cases of intussusception per 100,000 recipients of the first dose.” Pet. Ex. 17 at 8; Pet. Ex. 24.³⁰

Dr. Santoro acknowledged that further research is needed to increase the understanding of the pathogenesis and etiology of intussusception. Pet. Ex. 17 at 9. However, he submitted that a mice study suggested that rotavirus infection enhances tumor necrosis factor alpha and gamma interferon cytokine levels following the introduction of lipopolysaccharide. *Id.*; Pet. Ex. 27.³¹ Dr. Santoro interpreted this study as suggesting rotavirus infection and vaccination with a live rotavirus vaccine can sensitize mice to the inflammatory effects of LPS treatment, thereby enhancing intussusception rates. *Id.* Further, ultrasound studies of infants with rotavirus infection have shown increased distal ileal wall thickness and lymphadenopathy, suggesting “a plausible mechanism by which Rotavirus infection could cause intussusception.” Pet. Ex. 17 at 9; Pet. Ex. 28.³²

Although E.E.D. was not diagnosed by his treating providers with an intussusception, Dr. Santoro submitted that he did have an intussusception on November 9, 2014. According to Dr. Santoro, following the Rotarix vaccine on November 5, 2014, E.E.D. developed diarrhea, severe pain, and lethargy and had feeding problems, GERD, and rectal bleeding (hematochezia).³³ Pet. Ex. 17 at 10. An abdominal scan showed a bowel obstruction. E.E.D. required an exploratory laparotomy to release the small bowel obstruction “and presumed intussusception”. Pet. Ex. 17 at 7, 10; Pet. Ex. 6 at 2072-73. During surgery, “kinking of the distal small bowel was noted just proximal to the ileocecal valve”, and Dr. Santoro opined this “kinking was the remnants of an intussusception which was the cause of the small bowel obstruction.” Pet. Ex. 17 at 10; Pet. Ex. 30;³⁴ Pet. Ex. 34 at 2; Pet. Ex. 38 at 2-3.

Dr. Santoro agreed that intussusception presents with a “classic triad” of abdominal pain, vomiting, and currant jelly stool but referenced *Carty* which showed only one to two-thirds of patients present with these symptoms. Pet. Ex. 34 at 2; Resp. Ex. D.³⁵ However, he also

²⁹ Eric S. Weintraub, M.P.H. et al., *Risk of Intussusception After Monovalent Rotavirus Vaccination*, 370 NEW ENG. J. MED 513 (2014), filed as “Pet. Ex. 23”.

³⁰ W. Katherine Yih, Ph.D., M.P.H. et al., *Intussusception Risk After Rotavirus Vaccination in U.S. Infants*, 370 NEW ENG. J. MED 503 (2014), filed as “Pet. Ex. 24”.

³¹ Kelly L. Warfield et al., *Rotavirus Infection Enhances Lipopolysaccharide-Induced Intussusception in a Mouse Model*, 80 J. VIROLOGY 12377 (2006), filed as “Pet. Ex. 27”.

³² Robinson et al., *supra* note 8.

³³ The records Dr. Santoro cited only support that E.E.D. presented with diarrhea. The other symptoms were not reported. Pet. Ex. 6 at 2010-13.

³⁴ Emrah Aydin, *Intussusception in a Preterm Newborn*, 59 PEDIATRICS AND NEONATOLOGY 312 (2018), filed as “Pet. Ex. 30”.

³⁵ H.M.L. Carty, *Paediatric Emergencies: Non-Traumatic Abdominal Emergencies*, 12 EUROPEAN RADIOLOGY 2835 (2002), filed as “Resp. Ex. D”.

submitted that E.E.D. presented with abdominal pain, vomiting, and rectal bleeding. Pet. Ex. 34 at 2-3.

Dr. Santoro further explained that the gold standard to diagnose an intussusception is ultrasound. Ultrasound is also required for evaluation of reducibility, presence, location, diagnosis, and exclusion of residual intussusception after enema, and identification of alternative diagnoses. It has a high accuracy at 98-100%. Pet. Ex. 34 at 2; Pet. Ex. 35;³⁶ Pet. Ex. 38 at 2-3. He pointed to a textbook edited by Dr. Liacouras which states that ultrasound is the suggested screening test. Pet. Ex. 36 at 2; Pet. Ex. 37;³⁷ Pet. Ex. 38 at 2-3. Here, only an x-ray was performed, which has a low sensitivity rate and is not recommended to diagnose intussusception. Pet. Ex. 34 at 2; Pet. Ex. 35. Thus, Dr. Santoro argued E.E.D.'s intussusception was missed because the "gold standard" diagnostic tests were not done". Pet. Ex. 36 at 2; Pet. Ex. 38 at 3.

Dr. Santoro further discussed the November 23, 2014 intraoperative endoscopy on the small and large bowel, which revealed normal appearing mucosa of the colon but stated that the distal small bowel was inflamed, thickened, and bleeding. Pet. Ex. 17 at 10; Pet. Ex. 6 at 2068-70. These findings were consistent with necrotizing enterocolitis, which he opined was caused by the intussusception. "It has been suggested that mesenteric and enteric vascular ischemia could be one trigger of intussusception in neonates." *Id.*; Pet. Ex. 29;³⁸ Pet. Ex. 34 at 3; Pet. Ex. 38 at 3. In other words, he believed the Rotarix vaccination caused an intussusception, which in turn "caused or precipitated" his subsequent NEC, which required surgical intervention. Pet. Ex. 34 at 3; Pet. Ex. 38 at 3.

He disagreed that E.E.D.'s small bowel obstruction resulted from adhesions caused by his prior laparoscopic fundoplication with gastrostomy placement because "adhesions only form after abdominal surgery". Pet. Ex. 34 at 3. He argued that the prior surgery was only a laparoscopic fundoplication—not an open procedure—and it was in the upper abdomen, not the lower abdomen where the obstruction occurred. *Id.*; Pet. Ex. 36 at 2. He added that even the literature Dr. Liacouras submitted states that the risk of adhesions is low after laparoscopic surgery in children. Pet. Ex. 36 at 2; Resp. Ex. L;³⁹ Resp. Ex. M.⁴⁰

In summary, Dr. Santoro argued the medical theories and experimental evidence he provided shows the mechanism by which rotavirus vaccine, specifically Rotarix, can cause intussusception and bowel obstruction in certain patients and satisfies prong one. Pet. Ex. 17 at 11. According to Dr. Santoro, prior to the November 5, 2014 rotavirus vaccine, E.E.D. had no prior history of small bowel obstruction or intussusception. But within three days of receiving the rotavirus vaccine, E.E.D. suffered a small bowel obstruction due to intussusception. In his opinion, the Rotarix vaccine caused the intussusception and bowel obstruction, as well as the sequela of these injuries as detailed in the medical records in satisfaction of prong two. *Id.* There is no other more likely identifiable cause in the records. Pet. Ex. 34 at 3; Pet. Ex. 38 at 3. Finally,

³⁶ Applegate, *supra* note 10.

³⁷ Kelly, *supra* note 6.

³⁸ Hirokawa et al., *supra* note 18.

³⁹ Ngozi J. Nwokoma, MRCS et al., *Trocar Site Adhesions After Laparoscopic Surgery in Children*, 19 SURGICAL LAPAROSCOPY ENDOSCOPY & PERCUTANEOUS TECHNIQUES 511 (2009), filed as "Resp. Ex. L".

⁴⁰ G. Polymeneas et al., *A Comparative Study of Postoperative Adhesion Formation After Laparoscopic vs. Open Cholecystectomy*, 15 SURGICAL ENDOSCOPY 41 (2001), filed as "Resp. Ex. M".

the literature shows that intussusception following rotavirus vaccination is most common within 7 days. Here, E.E.D. developed intussusception within 3 days of receipt of the Rotarix vaccine, thus satisfying prong three. Pet. Ex. 17 at 11.

B. Respondent's Expert, Dr. Chris Liacouras

Dr. Liacouras received his B.A. from Johns Hopkins University in 1981 and his M.D. from Harvard Medical School in 1985. Resp. Ex. B at 1. He completed a postdoctoral fellowship in pediatric gastroenterology and nutrition at Children's Hospital of Philadelphia ("CHOP"). Since then, he has been on faculty at Harvard Medical School, University of Pennsylvania School of Medicine, and at CHOP, serving in various capacities, including as a professor of pediatrics and as the Medical Director of CHOP Center for Gastrointestinal Endoscopy. *Id.* at 1-2; Resp. Ex. A at 3. He is board-certified in pediatric gastroenterology. Resp. Ex. A at 1. Dr. Liacouras has evaluated between 2000-3000 pediatric patients with all types of gastrointestinal disorders over the course of his career. *Id.* at 3. He has evaluated or consulted on more than 100 pediatric patients with intussusception. *Id.*

Dr. Liacouras issued three reports in this case. Resp. Ex. A; Resp. Ex. K; Resp. Ex. N. It is his opinion that E.E.D. had a small bowel obstruction on November 9, 2014, which was mostly likely due to complications from the various conditions he was born with. Resp. Ex. A at 6.

Dr. Liacouras detailed E.E.D.'s medical history in the first eight weeks of life and prior to his receipt of the rotavirus vaccination in which he was diagnosed with abdominal distention, hematemesis, distal bowel obstruction at 5 days of age, necrotizing enterocolitis requiring antibiotics, sentinel bowel loop, and severe gastroesophageal reflux disease requiring laparoscopic Nissen fundoplication and G-tube placement. Resp. Ex. A at 1-2.

Dr. Liacouras then detailed the medical events following the November 5, 2014 Rotavirus vaccine when E.E.D. was presented to the ER on November 9, 2014 with diarrhea and abdominal distention. An x-ray showed multiple loops of distended small bowel with air-fluid levels consistent with small bowel obstruction. Surgery was performed to release a kink of the terminal ileum 5 cm proximal to the ileocecal valve and to evaluate the entire small bowel with no other abnormalities found. Specifically, "[t]hey did not find an intussusception." Resp. Ex. A at 3; Resp. Ex. K at 2; Pet. Ex. 6 at 2073. E.E.D. also tested positive for enterovirus and rhinovirus, which was most likely the cause of his diarrhea. Resp. Ex. A at 2; Resp. Ex. K at 2-3; Pet. Ex. 6 at 2047. He noted that E.E.D.'s symptoms were not consistent with the classic triad of intussusception. Resp. Ex. K at 2-3. Abdominal ultrasound performed on November 10, 2014 revealed "numerous loops of fluid-filled dilated bowel in the abdomen without intussusception." Resp. Ex. A at 2; Pet. Ex. 6 at 2060. A CT performed on November 14, 2014 showed the same. *Id.*

E.E.D. continued to have persistent abdominal distention, sepsis, and bloody stools, he required another abdominal surgery on November 23, 2014. Resp. Ex. A at 2. The operative report for that surgery documented extensive lesions throughout the abdomen involving primarily the small bowel except for the very first 10 cm or so of the jejunum beyond the

ligament of Treitz which was normal, thin-walled, and without adhesions. The remainder of the small bowel had thick, indurated, hyperemic dense adhesions in numerous places. Enterotomy was made in the mid ileum during adhesiolysis, and the surgeon noted blood-tinged fluid. Utilizing the enterotomy and a colotomy in the rectosigmoid, an on-table enteroscopy was performed on the entire colon and small bowel. There was an area of bright colored blood without active bleeding. The rest of the bowel was normal. There was no Meckel's diverticulum or intussusception noted. Resp. Ex. A at 2; Pet. Ex. 6 at 2069. E.E.D. remained hospitalized until December 22, 2014 requiring significant hospital support, close observation, and antibiotics. Between December 22, 2014 and December of 2015, he had multiple hospitalizations for bowel obstruction status post ileostomy and re-anastomosis, multiple PICC line infections, RSV, and C. difficile requiring two fecal transplants. He was diagnosed with Hirschsprung's disease requiring aggressive medical therapy. Resp. Ex. A at 2-3.

Based on his clinical experience with intussusception, the medical records, and literature, Dr. Liacouras opined that there is no evidence that E.E.D. suffered an intussusception nor was he diagnosed with intussusception. Resp. Ex. A at 3.

Dr. Liacouras distinguished a "kink" or bowel obstruction from intussusception. He explained that a "kink in the bowel" refers to a mechanic abnormality involving an anatomical twist or compression of the intestines. Resp. Ex. N at 3. Bowel obstructions have many causes including viral illness, adhesions, and NEC to name a few. Resp. Ex. K at 3. Medical literature has demonstrated that kinks in the bowel have no relationship to intussusception. Resp. Ex. N at 3; Resp. Ex. P;⁴¹ Resp. Ex. Q;⁴² Resp. Ex. R;⁴³ Resp. Ex. S;⁴⁴ Resp. Ex. T;⁴⁵ Resp. Ex. U.⁴⁶ An intussusception, on the other hand, is an acute emergent condition in which the bowel prolapses within itself. Resp. Ex. A at 4. It is common between 4 months to 2 years of age, but its cause is unknown. Children with intussusception usually present with a "triad" of symptoms which include severe abdominal pain, vomiting, and currant jelly stools. Intussusception is diagnosed by ultrasound, CT scan, or barium enema and initially treated with air, water, or contrast enema. Surgery is rarely required. Where surgery is required, intussusception—if present—would always be identified and corrected. Resp. Ex. A at 4, 5-6; Resp. Ex. K at 2-3.

While intussusception can cause a bowel obstruction, there was no clinical, radiological, or surgical evidence in this case to support an intussusception. Rather, E.E.D. suffered a mechanical "kink" in his intestine causing obstruction, more likely than not related to his many gastrointestinal issues that predated his receipt of the Rotavirus vaccination. Resp. Ex. A at 6;

⁴¹ Pierre Munier et al., *Bidirectional Jejunojejunal Anastomosis Prevents Early Small Bowel Obstruction Due to the Kinking After Closure of the Mesenteric Defect in the Laparoscopic Roux-en-Y Gastric Bypass*, 28 OBESITY SURGERY 1838 (2018), filed as "Resp. Ex. P".

⁴² Zana Alattar et al., *Proximal Small Bowel Obstruction in a Patient with Cystic Fibrosis: A Case Report*, 5 SURGICAL CASE REPORTS 143 (2019), filed as "Resp. Ex. Q".

⁴³ K.H. Ng, F.R.C.S. et al., *Obstructive Complications of Laparoscopically Created Defunctioning Ileostomy*, 51 DISEASES OF THE COLON & RECTUM 1664 (2008), filed as "Resp. Ex. R".

⁴⁴ Hisato Osada et al., *Multidetector CT Appearance of Adhesion-Induced Small Bowel Obstructions: Matted Adhesions Versus Single Adhesive Bands*, 30 JAPANESE J. RADIOLOGY 706 (2012), filed as "Resp. Ex. S".

⁴⁵ Mesut Sipahi et al., *Intestinal Malrotation: A Rare Cause of Small Intestinal Obstruction*, 2014 CASE REPORTS IN SURGERY 453128 (2014), filed as "Resp. Ex. T".

⁴⁶ de Vries et al., *supra* note 5.

Resp. Ex. K at 3; Resp. Ex. N at 2-3. Surgery on November 9, 2014 revealed “kinking” of the small bowel that was normal when the intestine was unkinked. Resp. Ex. A at 6. After surgery, his gastrointestinal symptoms continued and required a second surgery two weeks later, at which time multiple adhesions and inflammation were found. Resp. Ex. K at 3. None of the imaging performed showed any evidence of intussusception, nor was intussusception identified at any point during two surgical procedures. *Id.* at 4. Thus, he disagreed with Dr. Santoro’s characterization of the “kinking” of the small bowel as “remnants of an intussusception”. Resp. Ex. A at 5.

Dr. Liacouras explained that E.E.D. was born with several conditions that could have caused the small bowel obstruction. He had prior abdominal surgery related to severe GERD, NEC, and Cri-du-Chat. Resp. Ex. A at 5; Resp. Ex. K at 3; Resp. Ex. N at 1-2; Resp. Ex. O.⁴⁷ His prior surgery likely caused him to develop abdominal adhesions, which also could have caused his bowel obstruction. Resp. Ex. A at 4, 5-6; Resp. Ex. J;⁴⁸ Resp. Ex. N at 1-2. Dr. Liacouras concluded that E.E.D.’s small bowel obstruction was likely secondary to adhesions and ischemia from either the NEC or the Nissen fundoplication surgery he had during his first month of life. Resp. Ex. A at 4.

Dr. Liacouras detailed the inaccuracies in Dr. Santoro’s conclusions. First, E.E.D. did not have intussusception. Dr. Santoro presumed E.E.D. had intussusception but radiographic studies, including ultrasound and CT, as well as two surgeries never resulted in a finding or diagnosis of intussusception. Further, Dr. Santoro’s reliance on *Aydin* was misplaced because the patient discussed in *Aydin* was diagnosed with intussusception by ultrasound at the time of surgery. Resp. Ex. A at 5. He acknowledged that ultrasound or CT scans are the “gold standard” to diagnose intussusception but explained that those tests were unnecessary in this case because the plain abdominal x-ray showed the small bowel obstruction. Therefore, no additional testing was necessary. Resp. Ex. K at 1-2.

He further submitted that Dr. Santoro ignored E.E.D.’s medical history prior to his receipt of the vaccination, including several severe gastrointestinal disorders. Resp. Ex. A at 5; Resp. Ex. K at 1. Dr. Santoro further neglected to mention the adhesions found during the November 23, 2014 surgical procedure, which were more likely a complication of his NEC or secondary to the Nissen fundoplication and gastrostomy tube placement, both occurring prior to his vaccination. Resp. Ex. A at 6. Dr. Liacouras disagreed with Dr. Santoro’s assertion that laparoscopic fundoplication with gastrostomy placement would not cause adhesions or be associated with the bowel obstruction, stating that the procedure has decreased complications of adhesion formation, but it still occurs. Resp. Ex. K at 3; Resp. Ex. L.⁴⁹

Dr. Liacouras disagreed that E.E.D.’s intussusception resolved spontaneously or was reduced at the time of surgery, again pointing out that Dr. Santoro ignored the medical facts and the findings of the treating physicians in this case, none of which include intussusception. Resp.

⁴⁷ Paola Cerruti Mainardi et al., The Natural History of Cri du Chat Syndrome. A Report from the Italian Register, 49 European J. Medical Genetics 363 (2006), filed as “Resp. Ex. O”.

⁴⁸ Muhammad S. Choudhry & Hugh W. Grant, *Small Bowel Obstruction Due to Adhesions Following Neonatal Laparotomy*, 22 PEDIATRIC SURGICAL INT’L 729 (2006), filed as “Resp. Ex. J”.

⁴⁹ Nwokoma et al., *supra* note 39.

Ex. N at 2. Further, the details of the operative report of the surgery performed on November 9, 2014 show that the bowel obstruction was released upon the initial evisceration of the bowel which freed the “kink” and released the obstruction, all of which occurred prior to “the running of the bowel” as suggested by Dr. Santoro. *Id.*; Pet. Ex. 6 at 2073.

Dr. Liacouras argued all of Dr. Santoro’s opinions are based on assumptions not facts. Even if E.E.D. did have intussusception on November 9, 2014, the findings revealed during the November 23, 2014 surgery were consistent with NEC and were unrelated to intussusception. Resp. Ex. A at 6; Resp. Ex. K at 3. Dr. Liacouras disagreed that intussusception was the cause of E.E.D.’s NEC, noting that *Hirokawa* concluded that while the patient had both NEC and intussusception, the intussusception was not the primary cause of the NEC. Resp. Ex. K at 3; Pet. Ex. 29.⁵⁰ Further, intussusception would not cause the extensive adhesions seen throughout the vast majority of the abdomen during the November 23, 2014 surgery. Resp. Ex. K at 3. Still further, the location of E.E.D.’s small bowel disease could not be caused by a single intussusception but more likely was caused by NEC and his surgery prior to the vaccination. *Id.* at 3-4.

In sum, Dr. Liacouras opined that E.E.D. did not have intussusception and his rotavirus vaccination did not cause or contribute to his small bowel obstruction. He had Cri-du-Chat syndrome, necrotizing enterocolitis, and severe GERD with secondary aspiration requiring laparoscopic Nissen fundoplication prior to his vaccinations. Complications from these disorders can cause abdominal distention, adhesions, mucosal abnormalities, and small bowel obstruction. There is no evidence clinically or radiographically of an intussusception or any gastrointestinal symptoms caused by the rotavirus vaccine. Resp. Ex. A at 6; Resp. Ex. K at 4; Resp. Ex. N at 4. Further, there is no literature to support that a distal intussusception can cause multiple bowel adhesions and/or focal bowel intestinal lesion in a different location which was found here. Resp. Ex. K at 4; Resp. Ex. N at 3. The complicated medical conditions E.E.D. was born with also resulted in his ongoing and worsening symptoms throughout his life. Resp. Ex. K at 4.

V. Legal Standard

A petitioner is required to establish their case by a preponderance of the evidence. 42 U.S.C. § 300aa-13(1)(a). The preponderance of the evidence standard requires a “trier of fact to believe that the existence of a fact is more probable than its nonexistence before [they] may find in favor of the party who has the burden to persuade the judge of the fact’s existence.” *Moberly v. Sec’y of Health & Human Servs.*, 592 F.3d 1315, 1322 n.2 (Fed. Cir. 2010) (citations omitted). Proof of medical certainty is not required. *Bunting v. Sec’y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991).

Distinguishing between “preponderant evidence” and “medical certainty” is important because a special master should not impose an evidentiary burden that is too high. *Andreu v. Sec’y of Health & Human Servs.*, 569 F.3d 1367, 1379-80 (Fed. Cir. 2009) (reversing a special master’s decision that petitioners were not entitled to compensation); *see also Lampe v. Sec’y of Health & Human Servs.*, 219 F.3d 1357 (Fed. Cir. 2000); *Hodges v. Sec’y of Health & Human Servs.*, 9 F.3d 958, 961 (Fed. Cir. 1993) (disagreeing with the dissenting judge’s contention that

⁵⁰ Hirokawa et al., *supra* note 18.

the special master confused preponderance of the evidence with medical certainty). At the same time, mere conjecture or speculation is insufficient under a preponderance of evidence standard. *Snowbank Enter. v. United States*, 6 Cl. Ct. 476, 486 (1984).

The Vaccine Act provides two avenues for petitioners to receive compensation. First, a petitioner may demonstrate a “Table” injury—i.e., an injury listed on the Vaccine Injury Table that occurred within the provided time period. 42 U.S.C. § 300aa-11(c)(1)(C)(i). “In such a case, causation is presumed.” *Capizzano v. Sec’y of Health & Human Servs.*, 440 F.3d 1317, 1320 (Fed. Cir. 2006); *see* § 13(a)(1)(B). Second, where the alleged injury is not listed on the Vaccine Injury Table, a petitioner may demonstrate an “off-Table” injury, which requires that the petitioner “prove by a preponderance of the evidence that the vaccine at issue caused the injury.” *Capizzano*, 440 F.3d at 1320; *see* § 11(c)(1)(C)(ii); *see also* *Wright v. Sec’y of Health & Human Servs.*, 22 F.4th 999, 1006 (Fed. Cir. 2022) (defining the term “residual effects” in the Act, as “detrimental conditions within the patient, such as lingering or recurring signs and symptoms” of the alleged vaccine injury, which are compensable). A petitioner need not show that the vaccination was the sole cause, or even the predominant cause, of the alleged injury; showing that the vaccination was a “substantial factor” and a “but for” cause of the injury is sufficient for recovery. *Pafford v. Sec’y of Health & Human Servs.*, 451 F.3d 1352, 1355 (Fed. Cir. 2006); *Shyface v. Sec’y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). Petitioners are not required “to eliminate alternative causes as part of establishing [their] prima facie case.” *Doe v. Sec’y of Health & Human Servs.*, 601 F.3d 1349, 1357-58 (Fed. Cir. 2010); *see Walther v. Sec’y of Health & Human Servs.*, 485 F.3d 1146, 1152 (Fed. Cir. 2007) (holding that a “petitioner does not bear the burden of eliminating alternative independent potential causes”). Once a petitioner has proven causation by preponderant evidence, “the burden then shifts to the respondent to show by a preponderance of the evidence that the injury is due to factors unrelated to the administration of the vaccine.” *Deribeaux ex rel. Deribeaux v. Sec’y of Health & Human Servs.*, 717 F.3d 1363, 1367 (Fed. Cir. 2013) (citing 42 U.S.C. § 300aa-13(a)(1)(B)).

To prove causation, a petitioner must satisfy the three-pronged test established in *Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274 (Fed. Cir. 2005). *Althen* requires that a petitioner show by preponderant evidence that a vaccination they received caused their injury “by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.” *Id.* at 1278. Together, these prongs must show “that the vaccine was ‘not only a but-for cause of the injury but also a substantial factor in bringing about the injury.’” *Stone v. Sec’y of Health & Human Servs.*, 676 F.3d 1373, 1379 (Fed. Cir. 2012) (quoting *Shyface*, 165 F.3d at 1352-53). Causation is determined on a case-by-case basis, with “no hard and fast per se scientific or medical rules.” *Knudsen v. Sec’y of Health & Human Servs.*, 35 F.3d 543, 548 (Fed. Cir. 1994). Petitioners are not required to identify “specific biological mechanisms” to establish causation, nor are they required to present “epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities.” *Capizzano*, 440 F.3d at 1325 (quoting *Althen*, 418 F.3d at 1280). “[C]lose calls regarding causation are resolved in favor of injured claimants.” *Althen*, 418 F.3d at 1280.

Each *Althen* prong requires a different showing. Under the first prong, a petitioner must provide a “reputable medical theory” demonstrating that the vaccine received can cause the type of injury alleged. *Pafford*, 451 F.3d at 1355-56 (citation omitted). To satisfy this prong, a petitioner’s “theory of causation must be supported by a ‘reputable medical or scientific explanation.’” *Andreu*, 569 F.3d at 1379 (quoting *Althen*, 418 F.3d at 1278). This theory need only be “legally probable, not medically or scientifically certain.” *Id.* at 1380 (emphasis omitted) (quoting *Knudsen*, 35 F.3d at 548). Nevertheless, “petitioners [must] proffer trustworthy testimony from experts who can find support for their theories in medical literature.” *LaLonde v. Sec’y of Health & Human Servs.*, 746 F.3d 1334, 1341 (Fed. Cir. 2014).

The second *Althen* prong requires proof of a “logical sequence of cause and effect.” *Capizzano*, 440 F.3d at 1326 (quoting *Althen*, 418 F.3d at 1278). Even if the vaccination can cause the injury, a petitioner must show “that it did so in [this] particular case.” *Hodges v. Sec’y of Health & Human Servs.*, 9 F.3d 958, 962 n.4 (Fed. Cir. 1993) (citation omitted). “A reputable medical or scientific explanation must support this logical sequence of cause and effect,” *Id.* at 961 (citation omitted), and “treating physicians are likely to be in the best position to determine whether a logical sequence of cause and effect show[s] that the vaccination was the reason for the injury,” *Paluck v. Sec’y of Health & Human Servs.*, 786 F.3d 1373, 1385 (Fed. Cir. 2015) (quoting *Andreu*, 569 F.3d at 1375).

The third *Althen* prong requires that a petitioner establish a “proximate temporal relationship” between the vaccination and the alleged injury. *Althen*, 418 F.3d at 1281. This “requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder’s etiology, it is medically acceptable to infer causation-in-fact.” *De Bazan v. Sec’y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). Typically, “a petitioner’s failure to satisfy the proximate temporal relationship prong is due to the fact that onset was too late after the administration of a vaccine for the vaccine to be the cause.” *Id.* However, “cases in which onset is too soon” also fail this prong; “in either case, the temporal relationship is not such that it is medically acceptable to conclude that the vaccination and the injury are causally linked.” *Id.*; see also *Locane v. Sec’y of Health & Human Servs.*, 685 F.3d 1375, 1381 (Fed. Cir. 2012) (“[If] the illness was present before the vaccine was administered, logically, the vaccine could not have caused the illness.”).

Finally, although this decision discusses some but not all the literature in detail, I have reviewed and considered all of the medical records and literature submitted in this matter. See *Moriarty ex rel. Moriarty v. Sec’y of Health & Human Servs.*, 844 F.3d 1322, 1328 (Fed. Cir. 2016) (“We generally presume that a special master considered the relevant record evidence even though [s]he does not explicitly reference such evidence in h[er] decision.”); *Simanski v. Sec’y of Health & Human Servs.*, 115 Fed. Cl. 407, 436 (2014) (“[A] Special Master is ‘not required to discuss every piece of evidence or testimony in her decision.’” (citation omitted)), *aff’d*, 601 F. App’x 982 (Fed. Cir. 2015).

A. Law Regarding Diagnosis

In *Broekelschen v. Sec’y of Health and Human Servs.*, 618 F.3d 1339, 1346 (Fed. Cir. 2010), the Federal Circuit recognized that in some circumstances, the special master may “first determine which injury was best supported by the evidence in the record before applying the *Althen* test.” This principle also means that a petitioner must establish that the vaccinee suffers the injury allegedly linked to the vaccination. *Lombardi v. Sec’y of Health & Human Servs.*, 656 F.3d 1343, 1353-54 (Fed. Cir. 2011).

V. Discussion

The outcome of petitioner’s case is dependent on a finding that E.E.D. suffered an intussusception. Petitioner must first establish that intussusception was the appropriate diagnosis of E.E.D.’s condition on November 9, 2014. Then, petitioner must present preponderant evidence that the Rotavirus vaccine E.E.D. received on November 5, 2014 was the cause in fact of his intussusception.

A. Diagnosis

The parties do not agree that E.E.D. suffered an intussusception. Petitioner alleges that E.E.D. suffered an intussusception resulting from his November 5, 2014 Rotavirus vaccine. Respondent agrees with the treating physicians and submits that E.E.D. had a small bowel obstruction, which was more likely than not caused by factors unrelated to vaccination.

Focusing on E.E.D.’s medical history from the days following the subject vaccine, the medical records show the following: E.E.D. was presented to the ER on November 9, 2014 with a history of watery diarrhea that began around noon the day before. Pet. Ex. 6 at 2009-10. He tested positive for enterovirus and rhinovirus and while in the ER and developed a sepsis-like clinical presentation. *Id.* at 2050-52. His abdomen was distended. *Id.* at 2012. X-ray showed a small bowel obstruction. *Id.* at 2013, 2029, 2034. “Exploratory laparotomy, release of small bowel obstruction” was performed on that day. *Id.* at 2020-21. The operative report indicated small bowel obstruction, with findings of terminal ileal obstruction. *Id.* at 2073. It also details the procedure, stating that the bowel was eviscerated which released the bowel obstruction; there were no adhesions but there was kinking at the terminal ileum about 5 cm proximal to the ileocecal valve, which was released by pulling the bowel out of the abdomen. *Id.* Progress notes documented a 3-month-old with a history of Cri-du-Chat, laryngomalacia, and gastrotomy with fundoplication on October 2, admitted with bowel obstruction on November 9, 2014. *Id.* at 2145.

E.E.D.’s hospital course thereafter was complicated. He continued to have abdominal distension and on November 20, 2014 developed bloody stools. Pet. Ex. 6 at 2020, 2273. Antibiotics were administered for suspected NEC. *Id.* at 2050. He underwent another laparotomy on November 23, 2014, with on-table push enteroscopy of the entire colon and small bowel, resection of the distal ileum with end ileostomy and ileal mucous fistula, as well as an incidental appendectomy. The G-tube was converted to a 10 French Anderson nasogastric tube for improved postoperative gastric decompression. *Id.* at 2068-69. The surgeons documented a 2-month-old, status post-laparotomy for post-operative “bowel obstruction on November 9, 2014

after remote history of fundoplication and gastrostomy. Persistent abdominal distention, sepsis and development of bloody stools without identifiable etiology necessitated laparotomy.” *Id.* There were findings of extensive adhesions throughout the entire abdomen involving primarily the small bowel with the exception of the very first 10 cm or so of the jejunum beyond the ligament of Treitz. The remainder of the small bowel had thick, indurated, hyperemic, dense adhesions in places. *Id.* No findings of intussusception were noted. *Id.* at 2069-70. He was discharged on December 22, 2014. *Id.*

The experts agreed that intussusception presents with a classic triad of symptoms, including abdominal pain, vomiting, and currant jelly stool. Pet. Ex. 34 at 2; Resp. Ex. A at 4, 5-6; Resp. Ex. K at 2-3. In support of his opinion that E.E.D. suffered an intussusception, Dr. Santoro described E.E.D.’s symptoms following receipt of the Rotavirus vaccine as severe pain, lethargy, and significant rectal bleeding (hematochezia), in addition to having feeding difficulty and GERD symptoms. Pet. Ex. 17 at 10; Pet. Ex. 34 at 2-3. None of these symptoms were documented anywhere in the record. When asked to address this, he argued that only one to two-thirds of intussusception patients present with the “classic triad” of abdominal pain, vomiting, and currant jelly stool. Pet. Ex. 34 at 2; Resp. Ex. D.⁵¹ Dr. Liacouras argued that E.E.D.’s symptoms on November 9 were not consistent with intussusception but were consistent with enterovirus and rhinovirus, both of which E.E.D. tested positive for during his hospital stay. Resp. Ex. A at 2; Resp. Ex. K at 2-3.

The experts also agreed that the “gold standard” diagnostic test for intussusception is ultrasound. Pet. Ex. 34 at 2; Pet. Ex. 36 at 2; Pet. Ex. 38 at 2-3; Resp. Ex. K at 1-2. Dr. Santoro argued that the treating physicians failed to diagnose E.E.D.’s intussusception because an ultrasound was not performed. Pet. Ex. 36 at 2; Pet. Ex. 38 at 3; Resp. Ex. K at 1-2. Dr. Liacouras submitted that other diagnostic testing clearly showed a small bowel obstruction so further diagnostic testing—namely an ultrasound—was not required. Resp. Ex. K at 1-2.

Dr. Liacouras further argued that intussusception “is always found during a surgical procedure”; here, no intussusception was found during E.E.D.’s surgery on November 9. Resp. Ex. A at 6; Resp. Ex. K at 4. Dr. Santoro contended that the intussusception was not found during the November 9 surgery because it had spontaneously resolved prior to surgery but would have been seen on ultrasound if it had been performed. He then argued the “kinking” of the distal bowel represented remnants of the intussusception just proximal to the ileocecal valve which was not diagnosed because of the insensitivity of x-rays in diagnosing intussusception. Pet. Ex. 17 at 10; Pet. Ex. 34 at 2; Pet. Ex. 38 at 2-3. Dr. Liacouras disagreed with this explanation, stating that a “kink” in the bowel and intussusception are not the same. Intussusception is a “telescoping” of the intestine, while a “kink in the bowel” refers to a mechanically abnormal anatomical twist or compression of the intestines. Resp. Ex. A at 6-7; Resp. Ex. N at 2-3. Literature has demonstrated that kinks in the bowel have no relationship to intussusception. Resp. Ex. N at 3. He again pointed out that two procedures were performed, neither of which showed evidence of intussusception. Resp. Ex. K at 4.

The evidence submitted in this matter shows that a small bowel obstruction is not equivalent to an intussusception. Intussusception is where one part of the intestine folds into

⁵¹ Carty, *supra* note 35.

itself, much like when the smaller part of a telescope collapses into the larger part of the telescope when it is closed. Pet. Ex. 28 at 2; Pet. Ex. 35 at 2;⁵² Pet. Ex. 37 at 5;⁵³ Resp. Ex. H at 2-3.⁵⁴ A small bowel obstruction or kink, on the other hand, is where there is a twist or compression of the intestine. Resp. Ex. N at 3. While an intussusception may result in a small bowel obstruction, none of the evidence submitted stated that a small bowel obstruction could result in an intussusception. Resp. Ex. H at 2.

E.E.D.'s symptoms as documented in the medical records, imaging results, and observations during surgery do not support that E.E.D. had an intussusception on November 9, 2014. Rather, the evidence as a whole shows that E.E.D. had a small bowel obstruction.

E.E.D.'s medical records show that he was presented to the ER on November 9, 2014 for one day of watery, non-bloody stools and a concern for dehydration. There was no report of severe abdominal pain, vomiting, or currant jelly stool. He tested positive for enterovirus and rhinovirus, either of which could explain his symptoms. Pet. Ex. 6 at 2009-10, 2050-52. An x-ray performed while in the ER showed a small bowel obstruction requiring surgery. *Id.* at 2013. It was noted that enterovirus was "[l]ikely the cause of his ileus/SBO". *Id.* at 2503. The findings during the exploratory laparotomy done that day were consistent with a kink in the small bowel at the terminal ileum that was easily reduced. *Id.* at 2020-21.

E.E.D. then developed NEC, abdominal distention, sepsis, and bloody stools, and he required another surgery performed on November 23, 2014. Pet. Ex. 6 at 2068-69. The surgeons documented a 2-month-old, status post-laparotomy for post-operative "bowel obstruction on November 9, 2014 after remote history of fundoplication and gastrostomy. Persistent abdominal distention, sepsis and development of bloody stools without identifiable etiology necessitated laparotomy." *Id.* There were findings of extensive adhesions throughout most of the abdomen involving primarily the small bowel. *Id.* No findings of intussusception were noted. *Id.* at 2069-70.

It is my responsibility to make credibility determinations in assessing the probative value of witness opinion and the evidence filed in a case. *See Porter v. Sec'y of Health & Human Servs.*, 663 F.3d at 1242, 1250 (Fed. Cir. 2011) ("[T]his court has unambiguously explained that special masters are expected to consider the credibility of expert witnesses in evaluating petitions for compensation under the Vaccine Act."). Dr. Liacouras provided a higher degree of expertise within pediatric gastroenterology and paid more attention to the details of E.E.D.'s medical records both before and after the vaccination in rendering his opinions, thereby making his opinions far more compelling than Dr. Santoro's.

Not only did I find Dr. Liacouras to be a more credible witness given his expertise, I also found that Dr. Santoro's opinions lacked foundation or support in the record. Dr. Santoro's opinion was that the intussusception was simply missed during imaging and spontaneously resolved prior his surgery on November 9, 2014. This opinion is inconsistent with the symptoms E.E.D. presented with, the findings on x-ray, and the findings during the exploratory laparoscopy

⁵² Applegate, *supra* note 10.

⁵³ Kelly, *supra* note 6.

⁵⁴ Jain & Haydel, *supra* note 7.

on November 9. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 118 S. Ct. 512, 139 L. Ed. 2d 508 (1997); *Snyder ex rel. Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706 (2009) (“ . . . nothing in either Daubert or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the ipse dixit of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.”).

Further, Dr. Liacouras’ opinion that E.E.D. suffered a small bowel obstruction—not an intussusception—was consistent with the opinions of his treating providers. The opinions of E.E.D.’s treaters are entitled to some weight on the issue of diagnosis. It has been noted that treater opinions are generally important in evaluating if preponderant evidence supports one diagnosis over an alternative. *Strong v. Sec’y of Health & Human Servs.*, No. 15–1108V, 2018 WL 1125666, at *20 (Fed. Cl. Spec. Mstr. Jan. 12, 2018) (internal citations omitted). Not only were the treating providers able to observe E.E.D. at the time he suffered these symptoms, but they also had the benefit of seeing inside E.E.D.’s abdomen during two surgical procedures. At no point was E.E.D. diagnosed with an intussusception by any of his treating providers, nor was the possibility of intussusception even raised anywhere in the medical records.

In sum, E.E.D. presented on November 9 with diarrhea and concern for dehydration—not any of the classic triad of symptoms associated with intussusception. Based on his clinical presentation, an x-ray was ordered. While the literature supports that ultrasound is the preferred diagnostic tool for intussusception, *Carty* wrote that “[o]nce a clinical diagnosis of obstruction is made and confirmed by plain radiographs, further investigation is not indicated.” Resp. Ex. D at 8.⁵⁵ Thus, an ultrasound was not necessary here because the x-ray showed clear evidence of an obstruction that required surgery. Pet. Ex. 6 at 2029, 2034. Further, Dr. Liacouras explained that if an intussusception is present, it will be observed during surgery. Resp. Ex. A at 6. Here, the operative notes from the November 9 surgery do not document an intussusception. Pet. Ex. 6 at 2073. Finally, E.E.D.’s treaters agreed with the diagnosis of small bowel obstruction, for which he was treated; none of his providers documented any concern for an intussusception. *Id.* at 2029, 2034, 2503.

Based on the foregoing, there is not preponderant evidence in this case to support a finding the E.E.D. suffered an intussusception on November 9, 2014. Instead, the evidence supports a small bowel obstruction.

B. *Althen* Analysis

As noted above, for petitioner to prevail on an “off-Table” claim, she must show by preponderant evidence that the claimed injury resulted from the vaccination at issue. *Capizzano*, 440 F.3d at 1320. Doing so shifts the burden to respondent to show that the injury was caused by factors unrelated to the vaccination. *Deribeaux*, 717 F.3d at 1367.

Presenting a sound and reliable theory is essential to petitioner’s case. A theory causally connecting the vaccine to the injury is the first *Althen* prong. When petitioner fails to establish this element, compensation is denied. *Boatmon v. Sec’y of Health & Human Servs.*, 941 F.3d

⁵⁵ *Carty*, *supra* note 35.

1351, 1360-62 (Fed. Cir. 2019). Moreover, the theory advanced for *Althen* prong one influences the remaining two *Althen* prongs. For the second *Althen* prong, which addresses whether a logical sequence connects the vaccine to the injury, special masters may consider whether the vaccinee responded in a way consistent with the theory being offered. *Hibbard v. Sec’y of Health & Human Servs.*, 698 F.3d 1355, 1364 (Fed. Cir. 2012); *Miller v. Sec’y of Health & Human Servs.*, 172 Fed. Cl. 762, 784 (2024) (finding special master did not err in denying entitlement when petitioner did not establish that she had immune complexes after asserting a theory involving immune complexes); *Dodd v. Sec’y of Health & Human Servs.*, 114 Fed. Cl. 43, 52-57 (2013); *La Londe v. Sec’y of Health & Human Servs.*, 110 Fed. Cl. 184, 205 (2013), *aff’d*, 746 F.3d 1334 (Fed. Cir. 2014). Similarly, the third *Althen* prong, which concerns timing, depends at least in part upon the theory being offered. *Langland v. Sec’y of Health & Human Servs.*, 109 Fed. Cl. 421, 443 (2013); *see also Koehn v. Sec’y of Health & Human Servs.*, 773 F.3d 1239, 1244-45 (Fed. Cir. 2014) (holding that special master was not arbitrary in finding an onset of injury seven months after vaccination was incompatible with a theory based upon cytokines). Without a defined theory, attempting to determine whether preponderant evidence supports the logical sequence or timing is difficult if not impossible.

Petitioner’s causation theory is predicated on a finding that E.E.D. had an intussusception and that his intussusception was caused by the Rotavirus vaccine. Dr. Santoro failed to proffer an opinion as to how a rotavirus vaccine could cause a small bowel obstruction, adhesions, or NEC in the absence of intussusception. Indeed, he only mentioned small bowel obstruction incidentally as it can be caused by an intussusception. *See generally* Pet. Ex. 17; Pet. Ex. 34; Pet. Ex. 36; Pet. Ex. 38. Likewise, with the exception of a single article related to Cri-du-Chat, all literature Dr. Santoro relied upon was related to intussusception. Thus, my finding that E.E.D. did not suffer an intussusception renders the issue of causation moot. “Because causation is relative to the injury, a petitioner must provide a reputable medical or scientific explanation that pertains specifically to the petitioner’s case, although the explanation need only be ‘legally probable, not medically or scientifically certain.’” *Broekelschen*, 618 F.3d at 1345 (quoting *Knudsen*, 35 F.3d at 548-49).

1. Petitioner Has Not Provided a Sound and Reliable Medical Theory

It is petitioner’s burden to prove a sound and reliable theory for how the vaccinations received on November 5, 2014 can cause the injury alleged in this case. *Pafford*, 451 F.3d at 1355-56 (citation omitted). In other words, Dr. Santoro was required to provide a sound and reliable theory for how the rotavirus vaccine (or any of the other vaccinations given on November 5, 2014) caused a small bowel obstruction or “kink”, adhesions, and subsequent NEC that required surgical intervention.

Even assuming arguendo that Dr. Santoro’s theory could be applied to bowel obstruction without intussusception, it still fails. Dr. Santoro provided a detailed review of prior vaccinations against rotavirus, stating they were associated with intussusception. Pet. Ex. 17 at 5-8. The RotaShield vaccine was suspended shortly after it hit the market due to infants developing intussusception after receiving it. *Id.* at 5. An investigation into this concern revealed that the risk of intussusception increased 20-30 times over the expected risk for otherwise healthy infants within two weeks following the first dose of the vaccine and 3-7 times over the expected risk

following the second dose of the vaccine. *Id.* The manufacturer of the RotaShield vaccination voluntarily withdrew it from the market. *Id.* at 6. Dr. Santoro provided no citations to support this history.

Next, the Rotateq vaccine hit the market in 2006. In approximately one year on the market, the FDA stated that 28 cases of intussusception were reported through VAERS in the U.S. in infants who received the vaccine. Pet. Ex. 17 at 6. There have been an additional 584 confirmed intussusceptions after administration of the Rotateq vaccine as reported through VAERS, demonstrating “a consistent relationship between the Rotateq vaccine and intussusception from its introduction to the present.” *Id.*; Pet. Ex. 19.⁵⁶

Finally, he discussed the Rotarix vaccine, which is the vaccine administered in this case. Pet. Ex. 17 at 7. He submitted the package insert for the Rotarix vaccine, stating that no risk of intussusception was observed in a pre-licensing study of 63,225 infants in Finland and Latin America; however, post-marking observational studies in Mexico, Brazil, and Australia showed a temporal association of 31 days between intussusception and the first dose of Rotarix, with a clustering of cases in the first 7 days after vaccination. *Id.*; Pet. Ex. 20 at 5, 9-10.⁵⁷

As a preliminary matter, VAERS reports and manufacturers’ package inserts are not entitled to much weight in assessing causation. Though VAERS is an important monitoring tool, its use in assessing causation is limited because anyone can report anything through VAERS, no matter how attenuated, and it can only provide support for a temporal relationship. It is well established that VAERS data does not prove causation. *See, e.g., Sullivan v. Sec’y of Health & Human Servs.*, No. 10–398V, 2015 WL 1404957, at *20 (Fed. Cl. Spec. Mstr. Feb. 13, 2015) (“Because of their passive nature and unverified claims, VAERS reports are too anecdotal and unscientific to have much probative value in establishing a causation theory”); *Tompkins v. Sec’y of Health & Human Servs.*, No. 10–261V, 2013 WL 3498652, at *16 (Fed. Cl. Spec. Mstr. June 21, 2013), *review denied sub nom., Tompkins v. United States*, 117 Fed. Cl. 713 (2014). Even the study Dr. Santoro provided acknowledges that “VAERS generally cannot assess causality of an adverse event after vaccination”. Pet. Ex. 19 at 2.

Further, in a leading case discussing the evidentiary weight of package inserts, one special master went so far as to declare that “federal regulations specifically preclude the contents of drug product labels, as reproduced in the [Physician’s Desk Reference], from serving as admissions regarding causation.” *Werderitsch v. Sec’y of Health & Human Servs.*, No. 99–319V, 2005 WL 3320041, at *8 (Fed. Cl. Spec. Mstr. Nov. 10, 2005). Relying upon regulations found at 21 C.F.R. § 600.80, *Werderitsch* reasoned that because the Food and Drug Administration requires manufacturers to list adverse occurrences regardless of causality, the listing of an event on a product insert does not support a finding of causation. *Id.*; *see also Salerno v. Sec’y of Health & Human Servs.*, No. 16–1280, 2020 WL 344163, at *13 (Fed. Cl. Spec. Mstr. May 29, 2020); *Bender v. Sec’y of Health & Human Servs.*, No. 11–693V, 2018 WL 3679637, at *31 (Fed. Cl. Spec. Mstr. July 2, 2018) (noting that “vaccine package inserts do not constitute causation evidence meriting significant weight”), *mot. for rev. denied*, 141 Fed. Cl. 262 (2019); *Coppola v. Sec’y of Health & Human Servs.*, No. 09–631V, 2012 WL 1118849, at

⁵⁶ Haber et al., *supra* note 24.

⁵⁷ GlaxoSmithKline, *supra* note 25.

*26 (Fed. Cl. Spec. Mstr. Mar. 7, 2012) (rejecting a petitioner’s reliance on vaccine package insert information as indicative of alleged vaccine causation).

Dr. Santoro further relied on a mouse study that showed that rotavirus infection increased serum tumor necrosis factor alpha and gamma interferon cytokine levels after lipopolysaccharide induction, suggesting that the rotavirus infection and live vaccination could sensitize mice to the inflammatory effect of subsequent LPS treatment, thereby enhancing intussusception rates in mice. Pet. Ex. 17 at 9; Pet. Ex. 27.⁵⁸ While the authors found an elevation in intussusception rates in mice given both rotavirus and LPS compared to LPS alone, they noted that “[t]he failure of rotavirus infection *without LPS administration* to induce intussusception in mice suggests that either rotavirus infection alone induced intussusceptions at a low rate that was not detectable in our studies, at different times than we examined, or that it was important in, but not sufficient to cause, intussusception.” Pet. Ex. 27 at 6-7 (emphasis added). Thus, this article does not support that rotavirus infection by itself plays any role in intussusception.

In another study relied on by Dr. Santoro, the authors found an increase in distal ileal wall thickness and lymphadenopathy during acute infection with rotavirus, suggesting “a plausible mechanism by which rotavirus infection could cause intussusception.” Pet. Ex. 17 at 9; Pet. Ex. 28.⁵⁹ However, Dr. Santoro failed to explain what role distal ileal wall thickness plays in intussusception or why the findings of this study involving infection were applicable here when discussing rotavirus vaccination. Notably, the authors stated that their findings related to rotavirus infection were consistent with prior studies that concluded adenovirus may affect the bowel wall, but the “role [of infections] in inducing intussusception remains unclear.” Pet. Ex. 28 at 4. Thus, there is a gap in Dr. Santoro’s theory, rendering it unpersuasive. *See Langland v. Sec’y of Health & Human Servs.*, 109 Fed. Cl. 421, 441 (2013) (stating that a persuasive medical theory “may require an explanation of the steps by which the vaccination was believed to result in the harm”).

Dr. Santoro cited to a case report of a premature infant with intussusception associated with NEC, submitting that mesenteric and enteric vascular ischemia could be a trigger of intussusception in neonates. Pet. Ex. 17 at 10; Pet. Ex. 29.⁶⁰ In reviewing the case report, the authors observed the possibility that NEC triggered intussusception—not the other way around. Pet. Ex. 29 at 2. Thus, the case report does not support Dr. Santoro’s argument that an intussusception caused by a rotavirus vaccine could in turn cause NEC that requires surgical intervention.

Even affording petitioner the benefit of the doubt that Dr. Santoro’s theory could be applied to small bowel obstruction without the presence of an intussusception, Dr. Santoro failed to explain how or by what mechanism vaccines in general or rotavirus vaccine specifically can cause intussusception, bowel obstruction, adhesions, or NEC. Likewise, he provided no literature to substantiate his threadbare theory that a rotavirus vaccine could cause any of the aforementioned injuries. The literature he cited only discusses rotavirus vaccination or infection associated temporally with intussusception. While petitioners are not required to demonstrate a

⁵⁸ Warfield et al., *supra* note 31.

⁵⁹ Robinson et al., *supra* note 8.

⁶⁰ Hirokawa et al., *supra* note 18.

“specific biological mechanism”, they “must proffer trustworthy testimony from experts who can find support for their theories in medical literature in order to show causation”. *LaLonde*, 746 F.3d at 1341; *see also Snowbank Enter.*, 6 Cl. Ct. at 486; *Moberly*, 592 F.3d at 1322; *de Bazan*, 539 F.3d at 1351.

Accordingly, petitioner has failed to present a sound and reliable theory for how the Rotarix vaccine can cause intussusception (which E.E.D. did not suffer), a bowel obstruction or “kink”, bowel adhesions, and/or NEC.

2. Petitioner Has Failed to Demonstrate a Logical Sequence of Cause and Effect as well as Proximate Temporal Relationship

Having failed to prove that E.E.D. suffered the injury alleged as well as a sound and reliable causation theory, the remainder of petitioner’s claim necessarily fails. But for the sake of thoroughness, the remaining prongs will be briefly addressed. Because petitioner’s arguments regarding prongs two and three significantly overlap, the prongs will be analyzed concurrently. As with prong one, I will assume for the sake of argument that petitioner’s theory can be accurately applied to a small bowel obstruction and not just an intussusception.

To satisfy prongs two and three, petitioner must demonstrate by preponderant evidence that the vaccination(s) did cause the injury alleged and that the onset of symptoms related to their injury occurred within a medically reasonable timeframe to infer causation. *Hodges v. Sec’y of Health & Human Servs.*, 9 F.3d 958, 962 n.4 (Fed. Cir. 1993) (citation omitted); *de Bazan*, 539 F.3d at 1352.

Dr. Santoro submitted that the rotavirus vaccine can cause an intussusception within seven days of its administration, which occurred here because E.E.D. received the subject vaccine on November 5 and suffered an intussusception three days later. He further opined that E.E.D.’s intussusception caused NEC which was surgically treated on November 23. Pet. Ex. 17 at 10-11.

In support of prong two, Dr. Santoro claimed that E.E.D. had not previously suffered an intussusception or a small bowel obstruction and there were no other more likely causes of his “presumed” intussusception. Pet. Ex. 17 at 7, 11; Pet. Ex. 34 at 3; Pet. Ex. 36 at 2-3. Further, he opined that the “kink” observed during E.E.D.’s November 9 surgery “represented the remnants of a resolved intussusception.” Pet. Ex. 38 at 2. He also opined that the intussusception caused E.E.D.’s subsequent NEC, requiring surgery on November 23. Pet. Ex. 17 at 11. To support both prongs two and three, Dr. Santoro argued that intussusception is most commonly seen within 7 days after rotavirus vaccination and E.E.D.’s intussusception occurred three days after his vaccination. *Id.*; Pet. Ex. 20;⁶¹ Pet. Ex. 21;⁶² Pet. Ex. 25.⁶³

Further, in support of prong two, Dr. Santoro submitted a study that demonstrated an increase in distal ileal wall thickness and lymphadenopathy during rotavirus infection. Pet. Ex.

⁶¹ GlaxoSmithKline, *supra* note 25.

⁶² Patel et al., *supra* note 26.

⁶³ Koch et al., *supra* note 11.

17 at 9; Pet. Ex. 28.⁶⁴ Dr. Santoro pointed out that the November 23 surgery showed inflammation, thickness, and bleeding in the distal small bowel. Pet. Ex. 17 at 10; Pet. Ex. 6 at 2068-70. However, Dr. Santoro failed to explain how distal ileal wall thickness leads to intussusception. Thus, even though the medical records support that E.E.D.'s distal small bowel was inflamed and thickened on November 23, it remains unclear how this relates to an intussusception. Further, the case report he provided to show an association between intussusception and NEC demonstrated only a one-way association, with NEC potentially causing intussusception not the other way around. Pet. Ex. 17 at 10; Pet. Ex. 29 at 2 (“ . . . mesenteric enteric vascular ischemia may produce a stricture following recovery from NEC. [One study] reported two possible cases of NEC evolving into intussusception . . . mesenteric and enteric vascular ischemia (i.e., NEC) may be one trigger of intussusception in neonates.”).⁶⁵ Thus, there is no evidence to support Dr. Santoro's contention that the intussusception caused E.E.D.'s NEC that necessitated surgery.

The remaining arguments in support of prongs two and three rely exclusively on temporal association. Pet. Ex. 17 at 7-8, 11; Pet. Ex. 20;⁶⁶ Pet. Ex. 21;⁶⁷ Pet. Ex. 25;⁶⁸ Pet. Ex. 34 at 3; Pet. Ex. 36 at 2-3. It is clearly established that temporal proximity alone is insufficient to prove causation. *Moberly*, 592 F.3d at 1323; *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992).

Therefore, even assuming that Dr. Santoro's theory regarding intussusception can be accurately applied to small bowel obstruction, I do not find it persuasive in proving either prongs two or three. At most, Dr. Santoro demonstrated a temporal relationship between intussusception and rotavirus vaccination. Although a proximate temporal relationship is part of the causation analysis, it alone is insufficient to meet petitioner's burden.

Despite Dr. Santoro's contentions, E.E.D. was unfortunately born with several conditions that could have caused his small bowel obstruction. I recognize that petitioner is not required to eliminate alternative causes to prove her prima facie case, but I would be remiss to not address the potential alternative causes in this case. *Stone*, 676 F.3d at 1379-80 (“Our decisions support the commonsense proposition that evidence of other possible sources of injury can be relevant not only to the ‘factors unrelated’ defense, but also to whether a prima facie showing has been made that the vaccine was a substantial factor in causing the injury in question.”); *de Bazan*, 539 F.3d at 1353 (“The government, like any defendant, is permitted to offer evidence to demonstrate the inadequacy of the petitioner's evidence on a requisite element of the petitioner's case-in-chief.”). In doing so, I also note that even without considering alternative cause(s), petitioner has failed to sustain her burden.

Importantly, Dr. Santoro failed to address E.E.D.'s prior medical history, even after he was explicitly ordered to do so. ECF No. 38. He disregarded the extensive, similar medical problems E.E.D. continued to suffer in the years following the 2014 hospitalization. He

⁶⁴ Robinson et al., *supra* note 8.

⁶⁵ Hirokawa et al., *supra* note 18.

⁶⁶ GlaxoSmithKline, *supra* note 25.

⁶⁷ Patel et al., *supra* note 26.

⁶⁸ Koch et al., *supra* note 11.

concentrated only on that which would support his opinion that E.E.D. suffered an intussusception resulting from a rotavirus vaccination, which was contrary to the medical record and findings of the treating physicians. Because Dr. Santoro was dismissive of, ignored and/or failed to address E.E.D.'s significant health issues, I afforded greater weight to the opinions of Dr. Liacouras. *See Porter*, 663 F.3d at 1250.

Dr. Liacouras explained that adhesions can cause a small bowel obstruction. In fact, adhesions are the leading cause of small bowel obstructions, with approximately 85% of adhesive small bowel obstructions caused by postoperative adhesions. Resp. Ex. S at 1.⁶⁹

The operative report from November 23, 2014 documented “extensive adhesions” throughout the abdomen involving primarily the small bowel with “thick, indurated, hyperemic dense adhesions”. Pet. Ex. 6 at 2068-70. Pneumatosis, which is a feature of NEC, was observed endoscopically and is not a complication of reducible intussusception. Resp. Ex. N at 3. Further, intussusception does not cause extensive adhesions throughout the entire abdomen. More likely, those findings resulted from NEC and prior surgery occurring prior to E.E.D.'s receipt of the subject vaccination. *Id.*; Resp. Ex. K at 3-4. Further, there is no literature to support that a distal intussusception can cause multiple bowel adhesions and/or focal intestinal lesion in a different location. Resp. Ex. K at 4.

There are several reasons to believe E.E.D.'s adhesions were related to his medical issues before vaccination. He was born with Cri-du-Chat, which often presents with gastroesophageal reflux that requires abdominal surgery. Dr. Liacouras cited literature discussing adhesions as part of the normal healing process following laparotomy. Resp. Ex. J at 1 (in a retrospective study of 414 babies who underwent transabdominal procedures in the weeks after birth, 23 or 6% had re-operations for small bowel obstructions due to adhesions, with four of those patients having further adhesive obstructions requiring surgery);⁷⁰ Resp. Ex. L at 2 (noting that 65-90% of patients with adhesive obstruction had undergone previous abdominal surgery whereas only 10-28% had no previous surgery).⁷¹ E.E.D. had his first abdominal surgery on October 2, 2014 and a second abdominal surgery on November 9, 2014. Pet. Ex. 6 at 40, 2020-21. Dr. Santoro disagreed that E.E.D.'s small bowel obstruction was caused by adhesions that formed after his first surgery, arguing that adhesions only form after open abdominal surgery and E.E.D. had a laparoscopic fundoplication with gastrostomy placement. Further, the prior surgery was in the upper abdomen, not the lower abdomen where the obstruction occurred. Pet. Ex. 34 at 2-3; Pet. Ex. 36 at 2; Resp. Ex. L; Resp. Ex. M.⁷² Dr. Liacouras agreed with Dr. Santoro that laparoscopic procedures produce fewer adhesions than open procedures, but he argued adhesions still occur in laparoscopic procedures. Resp. Ex. A at 5; Resp. Ex. K at 3; Resp. Ex. L; Resp. Ex. J; Resp. Ex. M at 3.

A laparoscopic Nissen fundoplication uses five trocars, one with the camera placed supra-umbilically and the other four placed in a semicircle beneath the costal arch.⁷³ Thus, there

⁶⁹ Osada et al., *supra* note 44.

⁷⁰ Choudhry & Grant, *supra* note 48.

⁷¹ Nwokoma et al., *supra* note 39.

⁷² Polymeneas et al., *supra* note 40.

⁷³ Wenliang Chen & David W. Rattner, *Laparoscopy and Laparotomy*, in TEXTBOOK OF GASTROENTEROLOGY

are five entry points—not limited to the upper abdomen as argued by Dr. Santoro. The following image illustrates the entry points for laparoscopic fundoplication:



The experts agreed that the findings from the November 23, 2014 surgery were consistent with NEC. Dr. Liacouras explained that NEC can cause adhesion formation, and inflammatory processes that tend to result in denser adhesions. Resp. Ex. N at 2; Resp. Ex. J at 3, 4.⁷⁴ Dr. Santoro argued that NEC was “caused or precipitated by the small bowel obstruction and intussusception”. Pet. Ex. 17 at 11; Pet. Ex. 30;⁷⁵ Pet. Ex. 34 at 3. Dr. Liacouras argued the adhesions were more likely a complication of E.E.D.’s prior NEC (diagnosed on September 4, 2014) or secondary to the Nissen fundoplication and gastrostomy tube placement (on October 2, 2014), both occurring well before his vaccination. Resp. Ex. A at 6; Pet. Ex. 6 at 40, 169. Dr. Santoro never acknowledged that E.E.D. had NEC, a bowel obstruction or surgery shortly after his birth, thus he failed to explain why he believed the adhesions seen during the November 23 surgery were unrelated to the NEC he was diagnosed with prior to receiving the vaccine.

Finally, according to Dr. Liacouras, some viral illnesses have been demonstrated to cause a small bowel obstruction. Resp. Ex. K at 3. When E.E.D. presented to the ER on November 9, 2014, he tested positive for enterovirus and rhinovirus. Pet. Ex. 6 at 2051.

Dr. Santoro failed to provide preponderant evidence that the rotavirus vaccine E.E.D. received on November 5, 2014 was in any way related to his “presumed” intussusception, small bowel obstruction, adhesions, or NEC requiring surgery. Dr. Liacouras, on the other hand, presented persuasive, evidence-based arguments that E.E.D.’s small bowel obstruction was caused by factors unrelated to the rotavirus vaccination. For the reasons explained above, I afford greater weight to Dr. Liacouras’ opinions than to Dr. Santoro’s. I make no finding as to what alternative cause is most supported by the evidence submitted because that is not relevant here as petitioner failed to prove a prima facie case of causation. As such, petitioner has failed to satisfy prongs two and three.

(Tadataka Yamada, 2009).

⁷⁴ Choudhry & Grant, *supra* note 48.

⁷⁵ Aydin, *supra* note 34.

VI. Conclusion

While I extend my deepest condolences to the Derkach family on the loss of E.E.D., based on the evidence, I conclude that petitioner has not provided preponderant evidence that she is entitled to compensation under the Vaccine Act. **The Clerk shall enter judgment accordingly.**⁷⁶

IT IS SO ORDERED.

s/ Mindy Michaels Roth

Mindy Michaels Roth
Special Master

⁷⁶ Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by each party filing a notice renouncing the right to seek review.